Research Department Ref #	
Date Received	

1

Shifa International Hospital, Shifa College of Medicine & Shifa College of Nursing

Research APPLICATION FORM

Research Department
Office: 0092-51-4603435
Fax: 0092-51-4863109
Email: researchdeparrment@shifa.com.pk
Located at Department of Medical Staff Affairs

IRB & Ethics Committee
Office: 0092-51-4603075
Fax: 0092-51-4863109
Email: irbshifa@shifa.com.pk
Located at Department of Pediatrics

A. Submission Category: (Please check all that apply).

☐ New Protocol: (Study never performed. Include all documents listed in Section B.)

☐ Renewal or Modifications (Please complete Form "B")

(Study has previously been approved by IRB. Include the IRB Approval letter.

Application for

☐ Full Review ☐ Expedite Review ☐ Exempt Review

B. Checklist

☐ Two Copies of Research Proposal Application Form with Checklist

☐ Two Copies of Research Protocol

☐ Two Copies of Data Collection Forms (surveys, questionnaires, telephone scripts, data collection)

☐ Two Copies of Patient Information Sheet and Informed Consent Form English with Urdu Translation

☐ Curriculum Vitae And/ Or Other Relevant Documents Evidencing Qualifications of Investigator(S) And Sub-Investigator(S) and all other study team members

☐ Approval from the Departmental Head

☐ Any additional document that require approval

☐ Copy of this application and study documents filed for personal record

A. COVER PAGE

TITLE OF PROPOSAL

TYPE OF PROJECT

- ☐ Human
- ☐ Diagnostic
- ☐ Laboratory
- ☐ Chart Review
- ☐ Therapeutic
- ☐ Others

PRINCIPLE INVESTIGATOR OTHER STUDY TEAM MEMBERS

Principal Investigator: (Person noted as Principal Investigator in the IRB approval notice.)

PI's Name (Degree)

_____

Title:

Department & Division _____

Tel No: _____ Fax: _____

Email: _____

Other Study Team Members

Name & Qualification	Title/Position	Department	Role in the study	Signature

Note: Please Attach Curriculum Vitae of all study team members

B. ABSTRACT

WHAT IS THE PURPOSE/SIGNIFICANCE OF THE STUDY? (Please also give a brief background)

WHAT ARE THE OBJECTIVES OF THE STUDY?

DESCRIPTION OF METHODS USED IN PROTOCOL

4

PATIENTS SELECTION CRITERIA (Inclusion& Exclusion Criteria)

DURATION OF THE STUDY

ADVERSE/SERIOUS ADVERSE EFFECTS / POTENTIAL HAZARDS
(Explain how these events would be managed and who will bear the cost?)

5

POTENTIAL RISK TO THE PARTICIPANTS OR COMMUNITY AS WHOLE

POTENTIAL BENEFIT TO THE PARTICIPANTS OR COMMUNITY AS WHOLE

EXPLAIN ANY ETHICAL ISSUES AND CONSIDERATIONS IN THE PROPOSAL

C. SOURCE OF FUNDING

☐ Funds Required (Complete Budget Form C)

☐ Sponsored

Please specify the name of the funding source: _____
For Sponsored Research please attach copy of Financial Agreement

D. SERVICES

Will services at SIH & SCM be utilized which are not considered part of routine medical care?

☐ No ☐ Yes

IF yes please check appropriate box

☐ Cath Lab ☐ Medical Records ☐ Non-Invasive Cardiology

☐ CT scan Services ☐ MRI ☐ Nursing/Patient Care

☐ General Radiology ☐ Pharmacy ☐ Nuclear Medicine

☐ Laboratory ☐ Ultrasound

☐ Other special Services or Equipment: (please specify) _____

Payment of Arrangements: If "Yes" is checked in the above section, an explanation of payment arrangements is required and must be included with this submission packet

E. SETTINGS/FACILITIES TO BE USED FOR THE STUDY (In case of multi-centered studies, kindly list the name of participating centers/countries) (Please check all that apply)

☐ Inpatient ☐ Outpatient

☐ Shifa Department (Please specify) _____

F. EXPLAIN WHAT MEASURES WILL BE TAKEN TO SAFEGUARD PATIENT'S/SUBJECT'S CONFIDENTIALITY

G. REFERENCES

H. DEPARTMENTAL APPROVAL

I agree to accept responsibility for the scientific and technical conduct of the proposed research and submission of progress reports if this application is approved. I agree to submit study progress report to the Research Department and inform the IRB of any new information.

PRINCIPLE INVESTIGATOR

NAME: _____

SIGNATURE & STAMP _____

DATE: _____

DESIGNATION: _____

DEPARTMENT: _____

MAILING ADDRESS: _____

TEL. NO: _____

FAX: _____

EMAIL ADD: _____

APPROVAL OF DEPARTMENTAL HEAD

I approve the participation of the concerned personnel of my department in this study and confirm that there is no conflict of interest within the department for this project.

NAME: _____

SIGNATURE & STAMP: _____

DATE: _____

DESIGNATION: _____

DEPARTMENT: _____

MAILING ADDRESS: _____

TEL NO: _____

FAX: _____

EMAIL ADD: _____